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KIRTON AND MCCONKIE
60 EAST SOUTH TEMPLE,
SUITE 1800
SALT LAKE CITY, UT 84111

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| EXAMINER |
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LANDAU, SHARMILA GOLLAMUDI

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| ART UNIT | PAPER NUMBER |
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1616

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06/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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| <p align="center">Office Action Summary</p> | Application No. 09/839,433 | Applicant(s) JENSEN ET AL. | |
| | Examiner Sharmila Gollamudi Landau | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 7, 8, 11, 12, 22 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7-8, 11-12, 22, and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ 5) <input type="checkbox"/> Notice of Informal Patent Application 6) <input type="checkbox"/> Other: _____. |
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DETAILED ACTION

Receipt of Amendments/Remarks and the Rule 1.132 Affidavit filed on 3/29/07 is acknowledged. Claims **1, 7-8, 11-12, 22, and 27** are pending in this application. Claims 2-6, 9-10, 13-21, 23-26, and 28-30 stand cancelled.

Claim Rejections - 35 USC § 112

1) The rejection of claims 12 and 27 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of applicant's amendments of 3/29/07.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2) Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended claim 12 to recite "wherein the ozokerite is present in an amount between about 5 percent by weight." This claim is indefinite since "between" denotes a range. A range typically recites a lower limit and upper limit. However, the claim only recites "between about 5%". Thus, it is unclear what the upper limit of the range is.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) The rejection of claims 1, 7-8, 11-12, 12, 22, and 27 under 35 U.S.C. 103(a) as being unpatentable over Jensen et al (6,589,514) in view of Vatter et al (6,224,888) is withdrawn in light of applicant's statement that the invention was owned by, or subject to an obligation of assignment to, the same entity at the time this invention was made. Therefore, the prior art is disqualified as prior art under 35 U.S.C. 103(c).

2) The rejections of claims 1, 7-8, 11-12, 22, and 27 under 35 U.S.C. 103(a) as being unpatentable over Tahitian Lip Balm (<http://www.noni-now.com>, copyright 1998-2003) in view of Fisher (Living Better, vol. 1 (5) 1998) in further view of JP2000-095663 to Kondo et al in further view of Vatter et al (6,224,888) is withdrawn in light of applicant's Rule 1.131 Affidavit filed 1/23/06 and 2/13/06 respectively. Upon further consideration, both Rule 1.131 Affidavits are found persuasive for the following reasons: The lip balm sold by Morinda has a 102(a) date as established by the Rule 1.131 Affidavit and applicants have established by the Rule 1.131 Affidavit that the lip balm is applicants' own work. MPEP 2131.01. Accordingly, the rejection is withdrawn.

3) The rejection of claims 1, 7-8, 11-12, 22, and 27 under 35 U.S.C. 103(a) as being unpatentable over Tahitian Noni Products (<http://www.noni-now.com>, copyright 1998-2003) in view of JP2000-095663 to Kondo et al in further view of Vatter et al (6,224,888) is withdrawn in light of applicant's Rule 1.131 Affidavit filed 1/23/06 and 2/13/06 respectively. Upon further consideration, both Rule 1.131 Affidavits are found persuasive for the following reasons: The Affidavit of 2/13/06 states on record that all the products used in the rejection were not manufactured or sold in the US prior to 5/24/00. Thus, the prior art, namely the Body Balance

Art Unit: 1616

Cream constitutes prior art under 102(a) as established by applicant. The Rule 1.131 Affidavit filed on 1/23/06 and 2/13/06 respectively states that all the products advertised by noni-now.com were conceived and reduced to practice by the applicants. MPEP 2131.01. Accordingly, the rejection is withdrawn.

4) Claims 1, 7-8, 11-12, 22, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP2000-095663 to Kondo et al in view of Elkins (Hawaiian Noni, 1998) in further view of Vatter et al (6,224,888).

JP teaches a plant extract such as *Morinda citrifolia* for external use. These plant extracts have various properties such as skin whitening abilities, antioxidants effects, and antimicrobial effects, which make them effective for external use. See abstract. The plant extract is utilized in the amount of 0.0005-5% and JP discloses the use of instant *Morinda citrifolia* in the amount of 4.8%. Note Table 2 and page 4 of the translation. The plant extract is extracted from the branch, trunk, bark, bloom, fruit (contains the juice), roots, or other dry matters. The fruit is exemplified. Note that the fruit contains the juice and the seed, which contains the oil. See page 3. The external applications taught are milky lotion, cream, a pack, foundation, **lipstick**, shampoo, and conditioner and in the form of a liquid, salve, gel, etc. See page 2 and examples. Kondo et al teach additives such as lower alcohols, polyhydric alcohols, oily components (paraffin, squalene, cetyl alcohol), antioxidants, surfactants, thickeners, astringents, UV absorbents (octyl methoxycinnamate), vitamins, etc. in the cosmetic compositions. See examples and page 4. Examples teach the squalene in the amount of 5% and octyl methoxycinnamate in the amount of 5%. It should be noted that linoleic acid and xeronine are inherent properties of *Morinda citrifolia*.

JP does not specify the part of the fruit utilized, i.e. the fruit seed oil or the fruit juice.

Further, the reference does not teach the instant ozokerite.

Elkins teaches the usage of noni for over hundreds of years for its therapeutic actions (antimicrobial, antioxidant, and emollient benefits). Elkins teaches that *all* parts of the noni plant such as the fruit, the seeds (which contains the oil), bark, leaves, and flowers are utilized. See page 9-11. One of the most prevalent uses of noni is as a skin healing agent due to the presence of proxeronine and the skin's response to it. See page 30.

Vatter teaches a cosmetic composition including skin care products that treat and care for the skin, i.e. moisturize or improve the condition of the skin. See column 2, lines 20-25. Further, Vatter teaches utilizing a "solidifying agent" that solidifies liquid base materials to be used in a cosmetic composition. This solidifying refers to the physical and/or chemical alteration of the liquid base material so as to form a solid or semi-solid at ambient conditions, i.e., to form a final composition, which has a stable physical structure and is deposited on the skin during normal use conditions. The selection of the particular solidifying agent for use in the cosmetic compositions will depend upon the particular type of composition desired, i.e., gel or wax-based, the desired rheology, the liquid base material used and the other materials to be used in the composition. The solidifying agent is preferably used in an amount from about 3% to about 20%. Solidifying agents include wax-like materials include cetyl alcohol, waxes including paraffin, ceresin, **ozokerite, white beeswax**, synthetic waxes, and **mixtures thereof**. The waxy materials may also serve as emollients. See column 8, lines 10-45. Additionally Vatter teaches an emollient as essential to the compositions. The emollient component aids in the application and adhesion of the composition to the skin and most importantly provides occlusive moisturization. Suitable oils

Art Unit: 1616

include esters, triglycerides, hydrocarbons and silicones are used in the amount of 5% to about 90% and most preferably from about 70% to about 90% of the emollient component. Petrolatum is specifically taught. See column 5, lines 20-25, column 6, line 9, and column 6, lines 55-60.

Firstly, although Kondo does not specify the part of the *Morinda citrifolia* fruit utilized, it is would have been obvious to one of ordinary skill in the art to look to the guidance provided by Kondo and Hawaiian Noni and utilize any part of the *Morinda citrifolia* extract in the cosmetic composition, i.e. the fruit seed oil and fruit juice. It should be noted that the fruit contains both the juice and the seed, which contains the oil. One would have been motivated to do so since JP teaches any part of the plant may be utilized and it will impart cosmetic benefits of skin whitening abilities, antioxidants effects, and antimicrobial effects. Hawaiian Noni also teaches that all the parts of the noni plant provide beneficial effects to the skin and have been used for years. Therefore, absent unexpected results, it would have been prima facie obvious for a skilled artisan to utilize all parts of the fruit in a composition and expect benefits to the skin.

Secondly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further look at the teachings of Vatter et al and utilize the instant ozokerite. One would have been motivated to do so with the expectation of success since Kondo teaches the composition may contain additional additives such as thickeners and oily components and Vatter teaches the use of wax hydrocarbon agents not only serve as emollients but also serve to change the rheology of the cosmetic composition to provide the desired structure to the cosmetic composition, i.e. a solid or semi-solid cosmetic. Therefore, it would have prima facie obvious to utilize the instant ozokerite in the cosmetic composition of Kondo for its dual purpose of serving as an emollient and its ability to change the physical structure of the composition to

Art Unit: 1616

yield a desired structure, i.e. it acts as a thickener. Moreover, it would have been obvious to further utilize petrolatum in the composition for the advantages taught by Vatter, which include providing adhesion of the composition to the skin, and provides occlusive moisturization. Lastly, a skilled artisan would have expected success by the instant combination since both references are in the same field of endeavor, i.e. skin care products used to moisturize and care for the skin.

Response to Arguments

Applicant argues that applicant has provided "Exhibit A" which includes research performed by applicant related to the unexpected efficacy of Noni seed oil and Noni juice in the claimed ranges. Therefore, applicant argues that the instant invention is unobvious over the unexpected results.

Applicant's arguments filed 3/29/07 have been fully considered but they are not persuasive. The examiner notes that Exhibit A only provides evidence supporting applicant's statement that the lip blam was not for sale prior to 5/24/00; however the Exhibit does not provide any evidence of unexpectedness. The Lab Sample does not describe the components in the formula or the amount of Noni juice in the formulation. The examiner cannot extrapolate any unexpectedness from the Exhibit A. Therefore, the rejection is maintained until applicant demonstrates the unexpectedness of the combination of the juice and oil in the instant weight ratio to overcome the obviousness rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

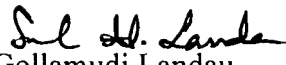
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1616


Sharmila Gollamudi Landau
Primary Examiner
Art Unit 1616

6/12/07